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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,898	04/15/2004	Paul D. Ziegler	P-11173.00	7576
27581	7590	02/06/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/824,898	<b>Applicant(s)</b> ZIEGLER ET AL.	
	<b>Examiner</b> Michael Kahelin	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01112006</u> .                                                            | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Specification***

1. The amendment to the specification is acknowledged and accepted. The objection is withdrawn.

### ***Response to Amendment***

2. The amendments to claims 4 and 14 are acknowledged.

### ***Claim Rejections - 35 USC § 112***

3. The amendments to claim 10 in response to the rejection under 112(2) are acknowledged and accepted. The rejection under 112(2) is withdrawn.

### ***Response to Arguments***

4. Applicant's arguments filed 1/11/2006 have been fully considered but they are not persuasive. In regards to independent claims 1, 10, and 11, Applicant argued that Bornzin et al. (US 5,549,650 hereinafter "Bornzin") does not anticipate the claimed subject matter because Bornzin's step of collecting 512 beats is not equivalent to delivering a pacing therapy for a time period and determining whether the therapy was delivered for a predetermined portion of the time period; that the amount of time the pacing therapy is delivered will depend on the intrinsic heart rhythm; and that the number of beats will depend on the intrinsic rate, pacing therapy rate, and portion of

Art Unit: 3762

time that pacing therapy is delivered. However, the "Fill Performance Matrix" routine shown in Figure 10 delivers a therapy at a fixed rate (col. 20, line 16) for a fixed number of beats (862), which will inherently result in a fixed time interval. Alternatively, the "time period" in its broadest reasonable interpretation can be interpreted simply as "the time required for 512 beats to be collected". During step 862, a counter is counting the beats, thus determining whether the therapy was delivered for a predetermined portion (all) of the time period.

5. In regards to claims 8 and 18, Applicant argued that the intrinsic heart rate may vary during the delivery of therapy, thus the event/rate data stored in the histogram as taught by Bornzin and Valikai et al. (US 5,948,005 hereinafter "Valikai") will not necessarily be stored according to first therapy rate and first time period and a next therapy rate and next time period, and that event/rate data may be stored in the same heart rate bins during the first and next time periods. However, Bornzin discloses (Fig. 11) discrete bins for a first therapy rate and first time period (512 beats) and next therapy rate and second time period. Figure 10 shows the flow of the algorithm that increments the therapy rate (874) to ensure that data is collected discretely for a first therapy rate over a first period and a next rate over a next period. The Valikai reference was relied upon simply for the teaching of measuring arrhythmia events, instead of Bornzin's cardiac output, as the dependent variable with respect to heart rate.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1- 5, 7, 9-15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (5,549,650).

8. In regards to claims 1, 10, and 11, therapy is delivered at a first rate (Fig. 10, 860) while a parameter is monitored (Fig. 10, 862), and it is determined whether the therapy was delivered for a predetermined portion of the first time period (Fig. 10, 862). This is repeated for a next rate over a next time period (Fig. 10, 874 to 876 to 878 to 862), and the optimal rate is determined (Fig. 9, 838). Please note that the examiner is interpreting the first and next time period as 512 beats times the number of AV “bins”, the parameter as cardiac performance, and the metric as delta P.

9. In regards to claims 2 and 12, the therapy is repeated for the first rate if the therapy is not delivered for the predetermined portion of the first time period (Fig. 10, 870 to 872 to 862).

10. In regards to claims 3 and 13, the therapy is repeated for the second rate if the therapy is not delivered for a predetermined portion of the next time period (Fig. 10, 870 to 872 to 862).

11. In regards to claims 4 and 14, repeated delivery at the first rate and repeated delivery at the second rate is repeated a predetermined number of times (Fig. 10, 880 to 882 to 884 to 862).
12. In regards to claims 5 and 15, the parameter corresponds to a hemodynamic event (col. 10, line 6). The examiner is interpreting a heart wall acceleration as a hemodynamic event.
13. In regards to claims 7 and 17, the therapy is delivered at the first rate and second rate during a second time period different from the first and "delta P" metrics are generated (Fig. 10, 880 to 882 to 884 to 862).
14. In regards to claims 9 and 19, one of the first rate and second rate is applied as the current therapy based on the first metric or second metric being less than the other by a threshold (col. 20, line 35).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 3762

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. in view of Mehra et al. (6,185,495). Bornzin et al. disclose the essential features of the claimed invention except for expressly disclosing that a predetermined number of arrhythmia events are detected before delivering a new therapy. Mehra et al. teach of an implantable device that initiates a new therapy based on the detection of a predetermined number of arrhythmic events in a predetermined period (col. 13) to provide a therapy that is an improvement over the existing therapy or lack of therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bornzin et al.'s invention by initiating a new therapy based on the detection of a predetermined number of arrhythmic events in a predetermined period to provide a therapy that is an improvement over the existing therapy or lack of therapy.

18. Claims 8, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. in view of Valikai et al. (5,948,005). Bornzin et al. disclose the essential features of the claimed invention except for measuring arrhythmic events as the first and next parameters. Valikai et al. teach of creating histograms based on heart rate and arrhythmic events (in the form of the resulting paced events) to minimize arrhythmic events based on heart rate. Therefore, it would have been obvious to one

Art Unit: 3762

having ordinary skill in the art at the time the invention was made to modify Bornzin et al.'s invention by optimizing with respect to arrhythmic events instead of cardiac performance to minimize arrhythmic events based on heart rate. Please note that, in regards to claim 20, the first two iterations of the algorithm in Figure 10 use a "first and next lower rate" because HR is initialized to  $HR_{min}$ , which is a "lower rate". When HR is incrementally increased, HR becomes the "next lower rate".

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Art Unit: 3762

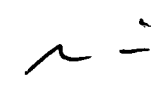
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

2/2/6